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5 IN THE UNITED STATES DISTRICT COURT
6 FOR THE NORTHERN DISTRICT OF CALIFORNIA7
8 FRESENIUS MEDICAL CARE
HOLDINGS, INC., et al.,

No. C 03-1431 SBA

9 Plaintiffs,

ORDER

10 v.

[Docket No. 473]

11 BAXTER INTERNATIONAL, INC., et al.,

12 Defendants.
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15 This matter comes before the Court on Defendants Baxter International, Inc. and Baxter
16 Healthcare Corporation's (collectively, "Defendants" or "Baxter") Motion to Strike Best Mode and
17 Anticipation Defenses, in Part, Under Local Patent Rule 3-7. Having read and considered the arguments
18 presented by the parties in the papers submitted to the Court, the Court finds this matter appropriate for
19 resolution without a hearing. The Court hereby DENIES Baxter's Motion to Strike Best Mode and
20 Anticipation Defenses, in Part, Under Local Patent Rule 3-7 [Docket No. 473].

BACKGROUND

21 On April 4, 2003, Plaintiffs and counter-defendants Fresenius USA, Inc. and Fresenius Medical
22 Care Holdings, Inc. (collectively "Fresenius") initiated this suit by filing a Complaint for Declaratory
23 Judgment of Non-infringement and Invalidity against defendants and counter-plaintiffs Baxter
24 International, Inc. and Baxter Healthcare Corporation (collectively "Baxter"). Fresenius cited five
25 patents in its Complaint: (1) U.S. Patent No. 5,247,434 ("434 Patent"); (2) U.S. Patent No. 5,326,476
26 ("476 Patent"); (3) U.S. Patent No. 6,284,131 B1 ("131 Patent"); (4) U.S. Patent No. 5,486,286 ("286
27 Patent"); and (5) U.S. Patent No. 5,744,027 ("027 Patent") (collectively "patents-in-suit").
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1 On May 14, 2003, Baxter answered and counterclaimed that Fresenius' 2008H and/or 2008K
2 hemodialysis machines infringed four of the five patents.

3 On October 9, 2003, pursuant to this Court's Patent Local Rules, Baxter served its Local Rule
4 3-1 Preliminary Infringement Contentions.

5 On October 20, 2003, Baxter amended its Answer and Counterclaims to assert infringement of
6 the '286 Patent.

7 On November 24, 2003, pursuant to Patent Local Rule 3-3, Fresenius served its Preliminary
8 Invalidity Contentions. After Fresenius filed a Motion to Compel Further Disclosures on December 22,
9 2003, Baxter served supplemental infringement contentions.

10 On October 14, 2004, a claim construction hearing was held on certain disputed terms.

11 On November 6, 2004, Fresenius served its second supplemental response to Baxter's
12 Interrogatory No. 6, which was intended to clarify "all basis [*sic*] for Fresenius' contention that the
13 patents-in-suit are invalid." Fresenius' second supplemental response to Interrogatory No. 6 contained
14 additional prior art references.

15 After the Court issued its claim construction ruling on November 22, 2004, the parties met and
16 conferred in order to narrow the selection of additional terms to be construed by the Court.

17 On December 28, 2004, Baxter served its Final Infringement Contentions pursuant to Local Rule
18 3-6(a).

19 On January 6, 2005, the parties requested that the Court construe the following additional claim
20 term from Claim 26(a) of the '434 Patent: "means for controlling a dialysate parameter selected from
21 a group consisting of dialysate temperature and dialysate concentration."

22 On January 18, 2005, Fresenius served its Final Invalidity Contentions pursuant to Patent Local
23 Rule 3-6(b). By filing its Final Invalidity Contentions, Fresenius added six new statutory theories of
24 invalidity, including the assertion that the "touch-screen claims" of the patents-in-suit¹ are invalid for
25 lack of enablement and failure to disclose best mode. Specifically, Fresenius' best mode and enablement
26 defenses were set forth as follows:

27
28 ¹The "touch-screen claims" are: claims 26-31 of the '434 Patent, claim 5 of the '476 Patent, claim
11 of the '027 Patent, and claims 1-3 and 13-16 of the '131 Patent.

Lack of Enablement Under 35 U.S.C. § 112(1)

The specification of the patents acknowledges that touch screens are well known in the art, and that the "use of touch screens in the user interface for medical equipment is also known." ('434 Patent, 8:21-24)[.] But during prosecution of the patents, the applicants argued that the touch-screen claims were nevertheless not obvious because applying a touch screen to a hemodialysis machine requires extensive innovation in hardware and software beyond a skilled artisan's ordinary knowledge.

The patent specification, however, fails to provide any teaching of such specialized hardware or software.

Failure to Disclose Best Mode Under 35 U.S.C. § 112(1)

[A]s noted above (and incorporated herein by reference), the applicants asserted numerous times during prosecution that applying a touch screen to a hemodialysis machine required extensive innovation in hardware and software. The specification fails to disclose the best mode to practice the extensively innovative hardware and software that the applicants asserted was required.

See Abernathy Decl. ISO Mot. to Strike at Ex. 1.

In its Final Invalidity Contentions, Fresenius also identified the Sarns 9000 Perfusion System (the "Sarns 9000"), including its operation manuals, as invalidating prior art that renders all of the touch-screen claims – including all of the asserted claims of the '131 Patent – obvious, and attached claim charts illustrating where specifically in the Sarns 9000 certain elements of the asserted touch screen claims are found. Abernathy Decl. ISO Mot. to Strike at Ex. 1.

On February 15, 2005, Baxter filed a Motion to Strike Fresenius' Final Invalidity Contentions.

On March 1, 2005, in opposing Baxter's Motion, Fresenius noted that:

Fresenius' discovery regarding the Sarns 9000 is ongoing. Since serving its final contentions, Fresenius has learned that heart lung machines such as the Sarns 9000 may have been used as or in conjunction with a hemodialysis system during cardiac bypass procedures. These uses of the Sarns 9000 may anticipate several of the asserted "touch screen" claims. Fresenius has timely produced information about these uses of heart lung machines as it has discovered the information, and will continue to do so.

Abernathy Decl. ISO Mot. to Strike at Ex. 2.

On July 15, 2005, Fresenius again supplemented its response to Baxter's Interrogatory No. 6. In its new supplemental response, Fresenius affirmatively identified the Sarns 9000 as both anticipating and rendering obvious the touch screen claims, and provided a detailed analysis. Abernathy Decl. ISO Mot. to Strike at Ex. 4. Baxter did not raise any objection to Fresenius' supplementation, or otherwise

1 question Fresenius' right to supplement its interrogatory response.

2 On August 24, 2005, the Court denied Baxter's Motion to Strike Fresenius' Final Invalidity
3 Contentions. The Court found that Fresenius' Final Invalidity Contentions complied with the Patent
4 Local Rules.

5 On September 26, 2005, Fresenius filed a Request for Ex Parte Reexamination Under 35 U.S.C.
6 § 302 and 37 C.F.R. § 1.510 for claims 1-25 of the '131 patent. Zheng Decl. ISO Opp. to Mot. to Strike
7 at Ex. F. In the Request for Reexamination, Fresenius argued that claim 1, the only independent claim
8 of the '131 Patent, and dependent claims 2-3, 5-6, 13-18, and 24-25, were obvious based on the Sarns
9 9000 in combination with a number of prior art references. Additionally, Fresenius asserted that claims
10 1, 2-3, 5-6, 13-18, and 24-25 were anticipated by the Sarns 9000. *Id.* Fresenius' Request for
11 Reexamination also included a claim chart setting forth on an element-by-element basis why the Sarns
12 9000 anticipates the asserted claims. *Id.* On September 28, 2005, Fresenius served a copy of the
13 Request for Reexamination and its appendices on Baxter's counsel. Zheng Decl. ISO Opp. to Mot. to
14 Strike at Ex. G.

15 On September 29, 2005, Fresenius served its sixth supplemental response to Baxter's
16 Interrogatory No. 6, in which Fresenius provided the same claim chart demonstrating, on an
17 element-by-element basis, the basis for Fresenius' belief that the Sarns 9000 anticipates each and every
18 asserted claim of the '131 Patent. Zheng Decl. ISO Opp. to Mot. to Strike at Ex. I. Baxter did not object
19 to Fresenius' supplemental response.

20 On November 17, 2005, Fresenius served its eighth supplemental response to Interrogatory No.
21 6. In the first full paragraph of page 14, Fresenius alleged that, "the named inventors knew that a
22 resistive touch screen was the best type of touch screen to use on a kidney dialysis machine, yet failed
23 to disclose this knowledge to the public through the disclosure of the asserted patents." Abernathy Decl.
24 ISO Mot. to Strike at Ex. 3.

25 On December 22, 2005, Fresenius served its opening expert reports regarding the invalidity of
26 the patents-in-suit. The opening expert report of Mr. James Causey provided a detailed analysis of the
27 grounds of invalidity of the asserted touch screen claims, including the basis for his conclusion that the
28 Sarns 9000 anticipates the asserted claims of the '131 Patent. Zheng Decl. ISO Opp. to Mot. to Strike

at Ex. J. On February 1, 2006, Baxter served its rebuttal expert reports, which challenged, among other things, Fresenius' contention that the Sarns 9000 anticipates all of the asserted claims of the '131 Patent. Zheng Decl. ISO Opp. to Mot. to Strike at Exs. L, M. Thereafter, the parties continued expert discovery with expert depositions. Mr. Causey was deposed by Baxter on February 22, 2006.

On February 21, 2006, Fresenius filed its Motion for Summary Judgment of Invalidity of the Asserted Claims of U.S. Patent Nos. 5,247,434 and 6,284,131. In the Motion, Fresenius seeks a summary judgment finding in its favor that, among other things, the Sarns 9000 anticipates the asserted claims of the '131 Patent under 35 U.S.C. § 102(b).

On March 7, 2006, the last day for filing dispositive motions, Baxter filed the instant Motion to Strike Best Mode and Anticipation Defenses. On the same day, Baxter filed a Motion for Partial Summary Judgment of Validity. In its Motion for Partial Summary Judgment of Validity, Baxter requests that the Court grant summary judgment in its favor on Fresenius' anticipation, enablement, and best mode affirmative defenses.

LEGAL STANDARD

The Northern District of California has adopted a comprehensive set of Patent Local Rules governing patent litigation. In general, the Local Rules exist to further the goal of full and timely discovery and provide all parties with adequate notice and information with which to litigate their cases. *Ixys Corp. v. Advanced Power Tech. Inc.*, 2004 WL 1368860 * 3 (N.D. Cal. 2004). "The rules are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *Atmel Corp. v. Information Storage Devices Inc.*, 1998 WL 775115 *2 (N.D. Cal. 1998).

Local Rule 3-3, which governs Preliminary Invalidity Contentions, provides as follows:

Not later than 45 days after service upon its of the 'Disclosure of Asserted Claims and Preliminary Infringement Contentions,' each party opposing a claim of patent infringement, shall serve on all parties its 'Preliminary Invalidity Contentions' which must contain the following information:

(a) The identity of each item of prior art that allegedly anticipates each asserted claim or renders it obvious

(b) Whether each item of prior art anticipates each asserted claim or renders it obvious. If a combination of items of prior art makes a claim obvious, each such combination, and the motivation to combine such items, must be identified;

(c) A chart identifying where specifically in each alleged item of prior

art each element of each asserted claim is found, including for each element that such party contends is governed by 25 U.S.C. § 112(6), the identity of the structure(s), act(s), or material(s) in each item of prior art that performs the claimed function; and

(d) Any grounds of invalidity based on indefiniteness under 35 U.S.C. § 112(2) or enablement or written description under 25 U.S.C. § 112(1) of any of the asserted claims.

N.D. Cal. Patent L.R. 3-3.

Local Rules 3-6 and 3-7 provide:

3-6. Final Contentions.

Each party's 'Preliminary Infringement Contentions' and 'Preliminary Invalidity Contentions' shall be deemed to be that party's final contentions, except as set forth below.

...

(b) Not later than 50 days after service by the Court of its Claim Construction Ruling, each party opposing a claim of patent infringement may serve 'Final Invalidity Contentions' without leave of court that amend its 'Preliminary Invalidity Contentions' with respect to the information required by Patent L.R. 3-3 if:

(1) a party claiming patent infringement has served 'Final Infringement Contentions' pursuant to Patent L.R. 3-6(a), or

(2) the party opposing a claim of patent infringement believes in good faith that the Court's Claim Construction Ruling so requires.

3-7. Amendment to Contentions.

Amendment or modification of the Preliminary or Final Infringement Contentions or the Preliminary or Final Invalidity Contentions, other than as expressly permitted in Patent L.R. 3-6, may be made only by order of the Court, which shall be entered only upon a showing of good cause.

N.D. Cal. Patent L.R. 3-6; N.D. Cal. Patent L.R. 3-7.

Pursuant to Local Rule 3-6, a party's Preliminary Invalidity Contentions are deemed to be the party's final contentions. N.D. Cal. Patent L.R. 3-6. Under Local Rule 3-7, however, a party may amend or modify its Final Invalidity Contentions upon a showing of good cause and by order of the Court.

ANALYSIS

In its Motion to Strike Fresenius' Best Mode and Anticipation Affirmative Defenses, Baxter moves to strike: (1) Fresenius' "touch screen" best mode defense; and (2) Fresenius' anticipation defense, to the extent that it relies on the Sarns 9000. Baxter also moves to strike the Declaration of Robert Phares (the "Phares Declaration"), which was submitted by Fresenius in support of its best mode defense. Baxter's Motion to Strike is premised on its belief that Fresenius' assertion of the aforementioned best

1 mode and anticipation defenses violates Patent Local Rule 3-7.

2 **A. Best Mode**

3 Baxter first argues that Fresenius' touch screen best mode defense should be stricken because
4 Fresenius failed to disclose this particular defense in its Final Invalidity Contentions. As Fresenius
5 points out, however, Baxter's argument is based on the flawed premise that the Patent Local Rules
6 require a party to disclose its best mode defense in its Final Invalidity Contentions. In fact, there is no
7 such requirement. *See* Patent L.R. 3-3. Patent Local Rule 3-3(d), which governs the disclosure of
8 invalidity contentions based on 35 U.S.C. § 112, only requires disclosure of indefiniteness, enablement,
9 or written description defenses.

10 The rationale for this clear; an accused infringer typically does not have the evidence necessary
11 to establish its best mode defense until much later in the discovery process. *See Dana Corp. v. IPC Ltd.*
12 *Partnership*, 860 F.2d 415, 418 (Fed. Cir. 1988) ("Whether or not a specific disclosure is adequate for
13 best mode purposes is determined by comparing the disclosure with the facts concerning the invention
14 known to the inventor at the time the application was filed."). Here, Fresenius contends that it did not
15 have an evidentiary basis for its best mode defense until September 2005, when it deposed Mr. Johnson,
16 one of the named inventors of the '131 Patent. Fresenius further contends that it engaged in exhaustive
17 due diligence efforts to determine whether the allegedly preferred embodiment pertaining to resistive
18 touch screens was mentioned in the patent specification, and that it took Baxter almost eleven weeks
19 to respond to Fresenius' inquiries. Moreover, Fresenius asserts that – as soon as it completed its
20 discovery efforts and concluded that the affirmative defense applied – it notified Baxter by
21 supplementing its interrogatory response.

22 Fresenius also argues that the submission of the Phares Declaration does not constitute "litigation
23 by ambush" because the declaration is not an alteration of Fresenius' best mode defense, but rather a
24 direct response to Baxter's contention that the Elographics part numbers in the specification "clearly
25 enumerat[e] a preference for a resistive touch screen." Fresenius further states it was not aware of the
26 fact that Baxter would claim that the Elographics part numbers evidence disclosure of a resistive touch
27 screen until February 1, 2006, when Fresenius received Mr. Ferraro's rebuttal expert report. Thus,
28 Fresenius contends that it had no reason to question Mr. Phares with respect to the part numbers on

1 November 2, 2005, or to ask Mr. Phares to address these particular numbers in his opening expert report
2 served on December 22, 2005. Additionally, Fresenius points out that the Phares Declaration merely
3 attests to the fact that the Elographics part numbers identified in the specification do not exist, a fact that
4 should come as no surprise to Baxter and is not reasonably in dispute.

5 The Court concludes that Fresenius is technically correct that the Patent Local Rules do not
6 impose an obligation on parties to disclose their best mode defenses in either their Preliminary or their
7 Final Invalidity Contentions. Further, the Court finds that allowing Fresenius to assert this
8 defense would not prejudice Baxter because: (1) Baxter is the most knowledgeable party with respect
9 to this defense; and (2) Baxter has already deposed Mr. Phares, Fresenius' key witness. Additionally,
10 and most importantly, the parties have already extensively briefed this issue for the Court. Accordingly,
11 the Court hereby DENIES Baxter's Motion to Strike Fresenius' best mode defense. The Court notes that
12 the Federal Circuit strongly encourages district courts to decide issues pertaining to invalidity when
13 those issues have been presented to the court, particularly because patent validity has important public
14 implications. *See Nestier Corp. v. Menasha Corporation-Lewis Systems Div.*, 739 F.2d 1576, 1581 (Fed.
15 Cir. 1984). Since this defense has been fully briefed by both parties, and since the Patent Local Rules
16 do not compel disclosure of a party's best mode defense, the Court has determined that it shall adjudicate
17 the defense on its merits. Therefore, the Court DENIES Baxter's request to strike the best mode defense
18 and the Phares Declaration.

19 **B. Anticipation**

20 Baxter next argues that Fresenius' anticipation defense pertaining to the Sarns 9000 must be
21 stricken because it was first asserted by Fresenius after Fresenius filed its Final Invalidity Contentions.²
22 In response, Fresenius argues that it has fully complied with the disclosure requirements under the
23 Patent Local Rules, and has also worked diligently to timely supplement its discovery responses, as
24 required by Rule 26(e) of the Federal Rules of Civil Procedure, in an effort to narrow and focus the
25 issues for trial.

26
27 ²Baxter also argues that Fresenius' anticipation defense should be stricken because it contradicts
28 the parties' agreed upon claim construction. This argument, however, is not a basis for striking the
defense under the Patent Local Rules.

Specifically Fresenius contends that it first discovered the Sarns 9000 on January 11, 2005 but did not know, at the time, that medical personnel sometimes perform dialysis during cardiopulmonary bypass surgery using a heart-lung machine. Fresenius also points out that the Sarns 9000 was disclosed to Baxter as a relevant piece of prior art when Fresenius filed its Final Invalidity Contentions on January 18, 2005. Although the Sarns 9000 was not disclosed as anticipating the asserted claims of the '131 Patent, Fresenius did inform Baxter in March 2005 that "[s]ince serving its final contentions, Fresenius has learned that heart lung machines such as the Sarns 9000 may have been used as or in conjunction with a hemodialysis system during cardiac bypass procedures. These uses of the Sarns 9000 may anticipate several of the asserted 'touch screen' claims." Abernathy Decl. ISO Mot. to Strike at Ex. 2.

Additionally, on September 29, 2005, Fresenius served its sixth supplemental response to Baxter's Interrogatory No. 6, in which Fresenius provided a claim chart showing, on an element-by-element basis, its contention that the Sarns 9000 anticipates each and every asserted claim of the '131 patent. Zheng Decl. ISO Opp. to Mot. to Strike at Ex. I. Fresenius also incorporated by reference its September 26, 2005 Request for Reexamination. Zheng Decl. ISO Opp. to Mot. to Strike at Ex. G. Subsequently, during expert discovery, Fresenius provided expert opinions as to why the Sarns 9000 anticipates the asserted claims of the '131 Patent. Baxter also submitted expert reports rebutting Fresenius' expert's opinion regarding whether the Sarns 9000 is anticipatory prior art. Finally, the parties both moved for summary judgment on this issue.

Due to Fresenius' clear intent to rely on this affirmative defense, it is not apparent to the Court why Fresenius did not, during the discovery period, formally request leave of Court to amend its Final Invalidity Contentions. Indeed, the Court finds that the best practice certainly would have been to do so. Equally inexplicable is Baxter's decision to wait until the very last possible moment to move to strike this defense. Nevertheless, since the parties have already engaged in extensive discovery pertaining to this affirmative defense, the Patent Local Rules' underlying goals of full and timely discovery and adequate notice have not been thwarted. Further, since the parties have both fully briefed this issue for the Court, Baxter does not appear to have been prejudiced by Fresenius' technical failure to comply with the Local Rules. Moreover, as noted above, district courts are strongly encouraged to decide issues pertaining to invalidity when presented. *See Nestier Corp.*, 739 F.2d at 1581. Thus, while

1 it is well within this Court's discretion to strike Fresenius' anticipation defense, given the procedural
2 posture of the case, the Court finds that the most expedient course of action is to DENY Baxter's Motion
3 to Strike Fresenius' anticipation defense and fully adjudicate the case on its merits.

4 **CONCLUSION**

5 Baxter's Motion to Strike Best Mode and Anticipation Defenses, in Part, Under Local Patent
6 Rule 3-7 [Docket No. 473] is DENIED.

7 IT IS SO ORDERED.

8
9 Dated: 5/15/06


SAUNDRA BROWN ARMSTRONG
United States District Judge